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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,943	06/26/2003	Kouji Hattori	239612US0	3410
22850	7590	01/14/2005	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.			CHANG, CELIA C	
1940 DUKE STREET			ART UNIT	
ALEXANDRIA, VA 22314			PAPER NUMBER	

1625

DATE MAILED: 01/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/603,943	Applicant(s) HATTORI ET AL.	
	Examiner Celia Chang	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 06 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-5, 7 and 11 is/are rejected.
- 7) ☐ Claim(s) 9 and 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of group I, claims 1-5, 7, 9-11 when B is phenyl or naphthyl in the reply filed on Oct. 6, 2004 is acknowledged. The traversal is on the ground that the examiner has not provided sufficient reasons in supporting burden. This is not found persuasive because in the restriction requirement, the diversified classes and subclasses have been clearly delineated in each group with "factual evidence" that the different core are not obvious variants but distinct structures for which searches are not *coextensive*. Such factual evidence is self explanatory in supporting "burden". Applicants were advised that "*should applicant traverse..., applicant should submit evidence....showing the groups or species to be obvious variants or clearly admit on the record that this is the case*". Applicants showed no factual evidence that either the independence or distinctness over the Hurmaus reference was wrong; nor the "burden" was obviated by art recognized evidence of obvious variants; or admit in the record such is the case.

The requirement is still deemed proper and is therefore made FINAL.

The scope of claims 1-5, 7, 9-11 when A is phenyl, B is phenyl or naphthyl are examined. Claims 6, 8 and the remaining subject matter of claims 1-5, 7, 9-11 are withdrawn from consideration per 37 CFR 1.142(b).

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hurnaus et al. CA 111:77643 or Shuker et al. CA 127:277798 supplemented by Greene.

See structure delineation from CA registry for the named compounds wherein R1 is H, or halogen, A is phenyl, B is phenyl, X is bond, O or CH₂, Y is bond, Z is carboxy or protected carboxy. Please note that the term "protected carboxy" inherently are esters or amides as defined by Greene on carboxy protecting groups.

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3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hurnaus et al. US 5,232,946.

Determination of the scope and content of the prior art (MPEP §2141.01)

Hurnaus et al. disclosed homolog compound of the instant claim, see col. 25, example 6 (see structural delineation of CA111:77643, RN121805-21-8 or 121805-22-9).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the claims and the prior art compound (see first compound of claim 5 and structural delineation of CA140:93927 RN643091-20-7) is that on the biphenyl ring, a hydrogen atom was replaced by one methyl group.

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would be motivated to modify the prior art compound with a one methyl addition since such modification is well recognized in the art to be within the sphere of obviousness that surrounds the prior art compound. In the *In re Wood* 199 USPQ 137 decision, the court has clearly set forth that the addition of a lower alkyl (methyl) group in place of a hydrogen would be considered structurally prima facie in absence of unexpected results.

4. Claims 9-10 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1 with respect to the elected subject matter. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim but the other substantial duplicates would be rejected as double patenting. See MPEP § 706.03(k). Please note that claims 9-10 contain all the compounds of claim 1 with the “intended use”. Intended use of a product does not bear weight since patentability of compounds must be the product per se i.e. elements, bonding arrangements, chemical structure. It is recommended that claims 9-10 be canceled.

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5. Claims 7 or 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is ambiguous as to the scope of the claim. Please note that the term "active ingredient" does not define any quantitative limitation of the composition. It is self conflicting that claim 7 is a "pharmaceutical" composition without a "therapeutically" effective quantity of the active compound since a "pharmaceutical" composition can neither be ineffective nor toxic. It is recommended that the term "therapeutically effective amount" be employed.

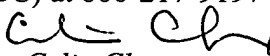
Claim 11 is confusing as to what is the claimed method and who is the subject being treated. Please note that the "subject" must be a human or animal in need of pollakiuria or urinary incontinence treatment because there is no good reason that unaffected subjects need to be treated. Once a human is in need of pollakiuria or urinary incontinence treatment i.e. being diagnosed with pollakiuria or urinary incontinence, the *prophylactic* treatment can only be preventing future occurrence of symptom of pathology which is part of the maintenance dosage encompassed by the term "treatment". It is recommended that the method for treating pollakiuria or urinary incontinence in a human or animal in need thereof be incorporated into the claim.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Jan. 11, 2005


Celia Chang
Primary Examiner
Art Unit 1625